UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM **March 21, 2017**

Subject: Technical Screen for New Ammonium Sulfate Product: Biosperse CX3400

PC Code(s): 005601	DP Barcode(s)/No(s): 436776
Decision No.: 522748	Registration Number (s): 74655-GO-Biosperse CX3400
Petition No(s).: NA	Regulatory Action: Technical Screen
Risk Assess Type: NA	Case No(s): NA
TXR No.: NA	CAS No(s): 7783-20-2
MRID No(s).: 50033606, 50033607, 50033605, various mammalian tox	40 CFR: NA

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The Agency has conducted a technical screen for the proposed new ammonium sulfate product, tradename Biosperse CX3400 (EPA Reg. No. 74655-GO) by Solenis LLC. This product is intended to be used as a microbiocide in the manufacture of paper and paperboard that contacts food, and in industrial water systems for control of algal, bacterial and fungal deposits. The proposed product label (received Oct 17, 2016) is attached at the end of this memorandum. The purpose of this technical screen is to determine whether the label and other information submitted with the application are sufficient to allow the assessment of human toxicology, occupational and residential exposure, ecological toxicity, and environmental fate as enumerated in 40 C.F.R. part 158 subpart W.

The registrant submitted waivers to use ammonium sulfate data for ecological toxicity and environmental fate data.. The application as submitted **passes** the technical screen in that the registrant provided citations or waiver rationales for the necessary data.

Mammalian Toxicology (Passes the Screen)

The registrant has cited mammalian toxicology data in support of the proposed uses of the product. The following mammalian toxicology data were cited by the registrant:

Acute Toxicity	**MRID**
OCSPP 870.1100 Acute Oral Toxicity	50033605
OCSPP 870.1200 Acute Dermal Toxicity	50033605
OCSPP 870.1300 Acute Inhalation Toxicity	50033605
OCSPP 870.2400 Primary Eye Irritation	50033605
OCSPP 870.2500 Primary Dermal Irritation	50033605
OCSPP 870.2600 Dermal Sensitization	50033605
Non-Acute Toxicity	
OCSPP 870.3100 90-Day Oral Toxicity in the rodent	48865603
OCSPP 870.3150 90-day Oral Toxicity in the non-rodent	waiver request
OCSPP 870.3200 90-Day Dermal toxicity in the rodent	waiver request
OCSPP 870.3465 90-Day Inhalation Toxicity in the rodent	48883401
OCSPP 870.3700 Pre-natal Developmental Toxicity-rat and rabbit	48865608/48865601
OCSPP 870.3800 Reproduction and Fertility Effects	48865607/48865602
OCSPP 870.4100 Chronic Toxicity in the rodent	48883401
OCSPP 870.4200 Carcinogenicity in the rodent	48883401
OCSPP 870.7485 Metabolism and Pharmacokinetics in the rodent	50033605
Mutagenicity	
OCSPP 870.5100 Reverse Mutation Assay	50033605
OCSPP 870.5300/5375 *In Vitro* Mammalian gene mutation	50033605
OCSPP 870.5385/5395 *In Vivo* cytogenetics	50033605
Immunotoxicity	
OCSPP 870.7800 Immunotoxicity	waiver request

The registrant has cited data and has made waiver requests for the toxicology data requirements. It is not known whether any of the data cited has been reviewed by the agency. The submission passes the screen for mammalian toxicology.

Dietary Exposure (Passes the Screen)

The proposed use of Biosperse CX3400 in pulp and paper mills involves indirect contact with food, as noted on the product label. In the September 14, 2012 Human Health Registration Review Scoping Document for Ammonia and Ammonium Sulfate (DP Barcode 404903, 401474) the Agency determined that in the pulp and paper water system, ammonium sulfate has low acute toxicity and the only potentially toxic compound resulting from this use of ammonium sulfate is chloramine. Any monochloramine not consumed in the pulp and paper water system is expected to degrade under the high temperature conditions of the paper drying process (110°C) and is not expected to remain in the paper to migrate to food. Further, monochloramine is not expected to be stable in surface water and so no drinking water exposure is expected from this use. Therefore, as concluded in the 2012 memorandum, based on no expected exposure, no dietary assessment nor aggregate (food plus water) assessment is needed at this time.

Occupational and Residential Exposure (Passes the Screen)

The registrant's proposed label and supporting information in the waiver request (MRID 50033607) addresses the exposure guidelines required under FIFRA (e.g. Series 875 exposure studies) and

therefore it passes the technical screen. As indicated on the proposed label, ammonium sulfate will be mixed with sodium hypochlorite in a Biosperse CX3400 feeder/delivery system to produce monochloramine onsite. The supporting information indicates that ammonium sulfate is transferred from the shipping container to the reactor via a closed system and therefore worker exposure to ammonium sulfate is not anticipated. It is also understood that the reaction will be optimized to produce monochloramine, which is non-volatile, while preventing the production of unwanted byproducts, such as trichloramine, which is volatile and toxic.

Table 1. Occupational and Residential Exposure Data Required for the Proposed Uses of Biosperse CX3400

Guideline No.	Study	Study/ Waiver submitted/ Data gap	Acceptable/ Unacceptable/ Pending review
875.1200	Dermal Exposure - Indoor	50033607	Acceptable
875.1400	Inhalation Exposure - Indoor	50033607	Acceptable
875.2400	Dermal Exposure – Post Application	50033607	Acceptable
875.2500	Inhalation Exposure – Post Application	50033607	Acceptable

Ecological Effects (Passes the Screen)

To support the TGAI, four acute ecotoxicology studies (avian, freshwater fish, invertebrate and green algae) are required by 158W. Those data are not needed for the risk assessment but are used to determine if precautionary statements are needed on the product label and to provide a basic data set in case of a spill or product misuse. The bird, fish, and aquatic invertebrate data are available.

A green algae toxicity test (850.4500) was not submitted and is required to support this use. However, since this PRIA action is for an existing use which was granted before 158W required green algae data for all uses, these data are being required through registration review.

The Agency has sufficient monochloramine ecotoxicity data for freshwater and estuarine/marine fish, invertebrates, and plants to support this use. Chronic ecotoxicity data are not available; however, because monochloramine rapidly biodegrades, chronic exposure is not anticipated and chronic data are not anticipated to be needed to support this PRIA action.

Environmental Fate (Passes the Screen)

Environmental fate data were not submitted as part of this data screen, but the registrant submitted acceptable data waivers in MRID 50033606. These waiver requests are appropriate because ammonium sulfate is a simple inorganic salt which is not expected to persist in the environment. In addition, ammonium sulfate is being used to generate an oxidant, monochloramine (MCA), which will be neutralized in effluent using sodium metabisulfite to form ammonium and chloride ions. The waiver requests are summarized in Table 2.

Table 2. Environmental Fate Waivers Submitted for the Proposed Uses of Biosperse CX3400

Guideline No.	Study	Study/ Waiver submitted/ Data gap	Acceptable/ Unacceptable/ Pending review
835.2120	Hydrolysis	50033606	Acceptable
835.2240	Photodegradation in Water	50033606	Acceptable

835.4300	Aerobic aquatic metabolism	50033606	Acceptable
835.4400	Anaerobic aquatic metabolism	50033606	Acceptable
835.1110	Activated sludge sorption isotherm	50033606	Acceptable
835.1230	Leaching-adsorption-desorption	50033606	Acceptable
835.3110	Ready biodegradability	50033606	Acceptable
850.3300	Modified Active Sludge Respiration Inhibition	50033606	Acceptable

Label received by email on Oct 17, 2016

[Master Label]
BIOSPERSE™ CX3400

MICROBIOCIDE FOR USE IN PULP AND PAPER MILL WATER SYSTEMS AND INDUSTRIAL WATER SYSTEMS

ACTIVE INGREDIENT
Ammonium Sulfate..……40.00%
INERT INGREDIENTS…….60.00%
TOTAL……...100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for further treatment advice.

If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water, if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Note: Have the product container or label with you when calling a Poison Control Center or doctor Hot Line Number: 1-844-SOLENIS (1-844-765-3647)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS
The pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a

National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS
Direct mixing of this product with sodium hypochlorite solutions and other strong oxidizing and alkali chemicals will release hazardous gases. Only mix with other chemicals or materials as specified in the Directions for Use of this product.

EPA Reg. No. 74655-
EPA Est. No, 74655-GA-001

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product must be used in conjunction with: 1) EPA registered sodium hypochlorite (12.5%) to produce monochloramine and 2) the Biosperse CX3400 feeder/delivery system, at a pH of $\geq$8.5, is programmed to automatically and optimally produce a dilute solution of monochloroamine. The installation, calibration and operation of the feeder/delivery system must be conducted only by Solenis authorized and trained personnel.

To achieve a minimum molar ratio of 1:1, Biosperse CX3400 to sodium hypochlorite, combine 1.0 liter (0.264 gallons) of Biosperse CX3400 to 3.7 liters (0.977 gallons) of sodium hypochlorite (12.5%). To ensure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water systems through a proper chemical feed skid only by a trained Solenis representative. Use of this product for any other purpose or contrary to the use directions specified below is prohibited.

PULP AND PAPER MILLS: This product is used as a microbiocide in the manufacture of paper and paperboard that contacts food. This product is applied in conjunction with sodium hypochlorite, using a closed delivery system, to form monochloramine, a slower acting less aggressive oxidizing microbiocide.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 1.0 liter (0.264 gallons) of Biosperse CX3400 to 3.7 liters (0.977 gallons) of sodium hypochlorite (12.5%). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 10 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems must be cleaned before initial treatment.

For continuous treatment, mix 1.0 liter (0.264 gallons) of Biosperse CX3400 to 3.7 liters (0.977 gallons) of sodium hypochlorite (12.5%). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of system oxidant demand (maximum of 10 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem. Badly fouled systems should be cleaned before initial treatment.

If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

INDUSTRIAL WATER SYSTEMS: Biosperse CX3400 is used for the control of algal, bacterial and fungal deposits in industrial recirculating cooling towers, recirculating cooling water systems, evaporative condensers, influent water systems, brewery and food pasteurizers, airwashers, reverse osmosis systems, paint spray booth sumps, non-fish containing decorative fountains and ponds used for cooling purposes.

When this product is used to treat recirculating cooling water systems, evaporative condensers, influent water systems (not part of once-through industrial water systems), brewery and food pasteurizers, airwashers, paint spray booth sumps, and non-fish containing decorative fountains and ponds used for cooling purposes; effluent detection of chloramine should be conducted at least once per shift. If chloramine is detected in the effluent, it can be neutralized by the addition of sodium metabisulfite until the chloramine is no longer detected.

Dosage Rates: When noticeably fouled, apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once control is achieved, treatment rates can be reduced to sub-demand rates from 50% to 80% of system demand. The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

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Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

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